EXHIBIT 1

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE)) MDL No.1456)
WHOLESALE PRICE LITIGATION) Master File No. 01-CV-12257-PBS
) Subcategory No. 06-CV-11337-PBS
)
THIS DOCUMENT RELATES TO:) Judge Patti B. Saris
U.S. of America ex rel. Ven-A-Care) Magistrate Judge Marianne B. Bowler
of the Florida Keys, Inc., et al. v.)
Boehringer Ingelheim Corporation, et al.,)
Civil Action No. 07-10248-PBS)
)

THE ROXANE DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION FOR A FINDING OF SPOLIATION OF EVIDENCE AND FOR SANCTIONS

In its response to Roxane's motion for spoliation sanctions, the DOJ effectively concedes that it both withheld and failed to preserve relevant evidence in this case—evidence that is the basis for the DOJ's attempt to inflate damages by nearly \$1 billion. After Roxane's motion for sanctions was filed, the DOJ belatedly produced some of that withheld evidence: (1) an incomplete subset of the Redbook compendia electronic CDs allegedly used by some of the Medicare carriers ("DMERCs") to classify drugs as generics or brands, and (2) a set of pricing arrays from one DMERC along with corresponding print-outs from the same Redbook CDs that the DMERC relied on to create its arrays during the relevant period. Incredibly, initial review of the material on these CDs and CD print-outs, which the DOJ claims led two DMERCs to conclude that Novaplus-label ipratropium bromide was a brand drug, reveals that these drugs were unambiguously classified on these Redbook CDs as generics. (See Exs. A, B)

Thus, the DOJ withheld from Roxane evidence that directly contradicts the DOJ's billion-dollar damages theory. And, even now, the DOJ has produced CDs from only two of the

four DMERCs, and the print-outs relied on to create arrays from only one DMERC, effectively admitting that there has been spoliation of evidence with respect to the other three. Such conduct is sanctionable. *See, e.g., Silvestri v. Gen . Motors Corp.*, 271 F.3d 583, 590-92 (4th Cir. 2001) (sanctioning litigant for destroying evidence after litigation became foreseeable); *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003) (same); *Taydus v. Cisneros*, 902 F. Supp. 288, 297 (D. Mass. 1995) (imposing sanctions for party's withholding of relevant documents); *Blake Assocs., Inc. v. Omni Spectra, Inc.*, 118 F.R.D. 283, 286 (D. Mass. 1988) (same).

The DOJ attempts to justify its failure to preserve and produce this critical evidence through a tortured reading of Roxane's discovery requests and a half-hearted argument that the evidence is "irrelevant." These arguments are frivolous, especially in light of the DOJ's prior and recent productions of hard copy print-outs from the same database. These materials were requested under any natural reading of Roxane's discovery requests. There can be no doubt that this evidence is not only relevant, but indeed critical to Roxane's defenses. These Redbook CDs are, according to the DOJ's theory in opposing summary judgment, the very basis upon which the DMERCs made the classification decisions on the Novaplus drugs that dramatically affect theoretical damages. The DOJ's most recent production confirms that at least one of the DMERCs relied exclusively on these CDs to create some of the pricing arrays at issue. The DOJ's failure to even confirm or acknowledge the existence of evidence that contradicts its claims until after Roxane filed a sanctions motion and its summary judgment motion is suggestive of the type of spoliation that warrants sanctions. See, e.g., Res. Trust Corp. v. S. Union Co., Inc., 985 F.2d 196, 197 (5th Cir. 1993) (affirming district court's grant of discovery sanctions where documents requested were not produced until after request for sanctions);

PepsiCo. v. Central Inv. Corp., Inc., 216 F.R.D. 418, 421 (S.D. Ohio 2002) (awarding sanctions where party withheld documents until after request for sanctions).

Similarly, the DOJ admits that it never bothered to obtain all of the State Medicaid claims data from the various State Medicaid agencies. The State Medicaid claims data was also requested by Roxane in discovery, and is critical evidence that reveals whether the Government overpaid providers *because of* Roxane's purportedly false AWPs and WACs. (*See* Dkt. No. 6425, Rox. SJ Reply 20-23) The DOJ attempts to blame *Roxane* for the DOJ's own failure to produce the Medicaid data—claiming that Roxane should have directly subpoenaed the states for the data. The DOJ's position flies in the face of its obligation under Rule 26 to conduct a reasonable search for documents within its "control" in response to a discovery request. Again, the DOJ's excuse falls woefully short.

ARGUMENT

The DOJ, like any other litigant, is required to follow the Federal Rules of Civil Procedure. *See United Med. Supply Co. v. United States*, 77 Fed. Cl. 257, 274 (2007). And, like any other litigant, the DOJ should be sanctioned for its noncompliance with those rules. *See id.* By refusing to obtain, preserve, and produce relevant evidence within its control, the DOJ has violated the discovery rules and engaged in sanctionable behavior.

I. THE DOJ ADMITS IT WITHHELD RELEVANT EVIDENCE.

A. The DOJ Unreasonably Withheld Redbook CDs From Roxane.

The DOJ's response to Roxane's motion and subsequent production of CDs from the Redbook electronic database make clear that the DOJ has withheld crucial evidence from Roxane. The DOJ does not dispute the following facts:

Without such data, the DOJ cannot meet its *prima facie* burden on causation. (Dkt. No. 6425, Rox. SJ Reply 20-23)

- The durable medical equipment regional carriers ("DMERCs") are government contractors that process Medicare claims for ipratropium bromide. (DOJ Opp. 3)
- The DOJ's duty to preserve evidence related to the DMERCs' processing of claims for ipratropium bromide reimbursement began, at minimum, in April 2000 when Ven-A-Care filed its complaint against Roxane. (Rox. Mot. 7)
- The DMERCs utilized CDs and electronic databases from the Redbook compendia in tandem with the printed paper volumes of the compendia, to construct their pricing arrays and to determine whether to classify drugs as brands or generics. The DMERCs then used these pricing arrays to determine the payment amount for ipratropium bromide, a subject drug. (*Id.* at 3-4)
- The DOJ took no steps to ensure that the DMERCs preserved these Redbook CDs or databases. (*Id.* at 5)
- The Administar DMERC representative testified that the data on the Redbook CDs was erased each time a new CD was loaded into the system. (*Id.*)
- Roxane served the DOJ with a discovery request seeking "all documents [including electronic documents and media] relating to how DMERCs or Medicare Carriers determined the payment amount for the Subject Drugs." (DOJ Opp. 4, 6-7 (citing Ex. C, 11/7/07 Rox. Doc. Reqs.) (emphasis added))
- Roxane never received a single Redbook CD or electronic database during fact discovery. Instead, Roxane received a handful of print-outs (with no discernible pattern) from certain Redbook CDs for certain carriers. (Rox. Mot. 5)

Rather than respond to these facts, the DOJ finally came forward with the actual Redbook CDs, which still existed and were in the possession of some of the DMERCs—where they have been throughout this *entire litigation*.² The DOJ claims that the material on these Redbook CDs led the CIGNA and Palmetto DMERCs to classify Novaplus-label ipratropium bromide as a brand product, rather than a generic: "from 1999 onwards, [the DMERCs] used quarterly CD-ROM updates to the Red Book, on which the 'Product Information screen' listed products according to their published names." ((DOJ Rox SJ Opp. 31) But the Redbook CDs in fact also

-4-

Until the DOJ actually produced these Redbook CDs, Roxane had always understood the data on them to be irretrievable because the Adminastar DMERC had testified that each updated quarterly CD effectively erased all the data on the prior CDs. As can now be shown, this is not the case. There are, however, still certain CDs in the DOJ's late production that are blank or otherwise inaccessible *See infra*. I.B.

contain the following "Detailed Product Information" about the Novaplus product, which specifically identified the Novaplus product as a *generic*—not a brand:

	Red Book(TM) for Windows®	Release: APRIL, 2002	
	Detailed Product Info		
	PRODUCT: MANUFACTURER: FORM: STRENGTH: ROUTE OF ADMIN: ORANGE BOOK CODE: ADD'L DESC: GENERIC NAME:	IPRATROPIUM BROMIDE-NOVAPLUS Roxane SOLUTION 0.02% INHALATION AN (S.D.V.,5X5, PROTECTAPAK) IPRATROPIUM BROMIDE	
→	NDC: 0005 SIZE: DEA Class: UNIT DOSE (Y/N): SINGLE SOURCE (Y/N): REPACKAGER (Y/N): ▼GENERIC (Y/N):	34-8404-11 2.500 ml 25s RX Y N N N	

As shown above, the Redbook CD contains a "Generic (Y/N)" field for the Novaplus drug that contains a "Y," indicating that the product is a generic. This, of course, is consistent with the overwhelming evidence that this product was *always* considered a generic product by Roxane, and recognized as such in the marketplace. (*See* Dkt. No. 6200, Rox. SJ Br. 24-25; Dkt. No. 6425, Rox. SJ Reply 11-19) Moreover, now that some of these Redbook CDs have finally been produced, it is clear that the precise compendia databases that the DOJ claims formed the basis for certain DMERCs' classifications of Novaplus ipratropium bromide as a brand actually documented the *opposite*. In fact, *every* accessible CD produced from the relevant period identifies Novaplus ipratropium bromide as a generic.³ (Exs. A, B) This new evidence contravenes the DOJ's litigation-driven theory that these products were properly classified as brands.

And these CDs also list other Novaplus products, such as Bumetanide Novaplus, Cytarabine Novaplus, Daunorubicin Novaplus, and Leucovorin Calcium Novaplus as generic products. (Ex. D)

The DOJ's new defense is that it did not allow this evidence to be destroyed, but merely withheld these crucial materials from its document production. (DOJ Opp. 6-7) This is no defense to sanctions, particularly given that these CDs contained critical material refuting the DOJ's claims. See Shaw Family Archives, Ltd. v. CMG Worldwide, Inc., 589 F. Supp. 2d 331, 345 (S.D.N.Y. 2008) (imposing sanctions where "[t]he withheld documents [were] clearly relevant to [plaintiff's summary judgment] motion, and defendants took a position in opposition to that motion that was directly contradicted by the withheld documents."); see also Taydus, 902 F. Supp. at 297; Blake Assocs., Inc., 118 F.R.D. at 286; PepsiCo., 216 F.R.D. at 421.

The DOJ attempts to justify its withholding of this evidence through a strained reading of Roxane's document requests, arguing that the Redbook CDs and databases did not fall within Roxane's broad request for "all documents [including electronic documents and media] relating to how the DMERCs set payment amounts" and by claiming that the Redbook CDs are "irrelevant." (DOJ Opp. 6-8) This is nonsense. First, the DOJ produced a small subset of hard copy print-outs from these same Redbook database during the fact discovery period. (See, e.g., Ex. E) Accordingly, its newfound argument that these Redbook databases are now "irrelevant" and were not responsive to Roxane's discovery requests are contradicted by the DOJ's prior discovery conduct. Second, the DOJ's litigation position is that the DMERCs used only these Redbook CDs to construct their pricing arrays during the time period that applies to the Novaplus drugs. Third, the relevance of the Redbook CDs is confirmed by the recent production of print-outs from the CDs attached to one DMERC's pricing arrays. (Ex. B) Thus, these Redbook CDs are allegedly the very basis upon which the DMERCs formulated their pricing arrays to "set payment amounts" and necessarily "relate to" how the DMERCs classified the Novaplus-label ipratropium bromide product as a brand (rather than a generic). (See Dkt. No.

6200, Rox. SJ Br. 12-25; Dkt. No. 6425, Rox. SJ Reply 11-19; Ex. F, Stone ¶ 11; Ex. G, Helton ¶ 31)

The DOJ's argument that Roxane did not "follow up" on its discovery request is also specious. As an initial matter, there is no requirement that a litigant press the DOJ to fulfill its discovery obligations. These CDs were required to be produced at the outset. Moreover, Roxane did in fact reiterate its request for Redbook materials during the March 2008 deposition of the CIGNA DMERC representative, and had no reason to ask yet again because the Adminastar DMERC's subsequent testimony established that the data on the Redbook CDs selfdestructed each quarter.⁴ (Rox. Mot. 5) Further, the DOJ did not amend its complaint to add the Novaplus products until after the DMERC testimony indicated to Roxane that these Redbook CDs did not contain accessible data—a contention the DOJ never corrected and which turns out to have been, at best, inaccurate. As discussed directly below, the DOJ conspicuously avoids that issue in its response. Simply, the DOJ should not be able to shirk its discovery obligations by somehow blaming Roxane for failing to see through the DOJ's game of "hide the ball." See Dziadkiewicz v. Blue Cross & Blue Shield of R.I., No. C.A. 96-275S, 2004 WL 2418308, *3 (D.R.I. Oct. 13, 2004) ("Defendant stands on the claim that Plaintiffs didn't ask just the right follow-up question in response to Defendant's employees' evasive and misleading answers . . . if they had, of course Defendant would have produced the data dictionary. These are just the kind of tactics that make complex litigation frustrating and time-consuming.")

DMERC representative Eiler testified: "when you put a new CD in the next quarter, then you cannot go back and access the previous." (Rox. Mot. 5 (citing 8/27/08 Eiler Dep 294-95) The DOJ's representation to this Court in December 2008 that "[t]here [was] also no need for any 'Medicare carrier' to be re-deposed" only confirmed Roxane's understanding that the DMERCs had no more relevant evidence to produce. (Master Dkt. No. 5732, Reply Br. in Supp. of Pls.' Mot. Leave to Amend Cplt. 3).

B. The DOJ Allowed The Destruction Of The Redbook Electronic Databases, Or, At A Minimum, Continues To Improperly Withhold Production.

The DOJ's response also effectively concedes that it failed to take adequate steps to preserve the Redbook databases, thus allowing them to be destroyed. Either that, or the DOJ continues to withhold Redbook CDs from production. As an initial matter, the DOJ fails to address Roxane's arguments regarding the DOJ's duty to preserve evidence or failure to implement any litigation hold until years after this lawsuit was filed, nor does the DOJ provide evidence of any direction given to the DMERCs to preserve the databases and CDs they received in 2001, a full year after this suit was commenced. (Rox. Mot. 5-7) As a result of the DOJ's failure to implement a proper litigation hold, it appears to have recovered Redbook CDs from only two of the four DMERCs. (Ex. H, Schedule of Redbook CDs attached to 8/21/09 G. Henderson Ltr. to E. Gortner) The DOJ has failed to produce Redbook CDs from DMERC-A and the Adminastar DMERCs, or explain the lack of production. Similarly, the DOJ has produced a full set of hard copy print-outs used to formulate the pricing arrays from only one DMERC. (Ex. B) It is unclear whether Redbook CDs and the corresponding print-outs from these other DMERCs have been destroyed or are being improperly withheld. In any event, there is no dispute that even at this late stage in this case, the DOJ's production is incomplete.

C. The DOJ Failed To Preserve Documents From The State Medicaid Agencies.

With respect to State Medicaid claims data, the DOJ does not dispute that its duty to preserve evidence related to its Medicaid claims arose when it filed suit against Abbott and Dey. (Rox. Mot. 7) Nor does the DOJ dispute that it failed to implement any systematic litigation hold or inform the states of the need to preserve claims data evidence. The DOJ also concedes that it failed to produce complete State Medicaid claims data for 31 states and any State Medicaid data from 18 other states. Instead, the DOJ protests that it "has never undertaken any

obligation to collect all available state-level Medicaid claims data" and that it had no "duty to preserve information in the possession, custody, and control of third parties." (DOJ Opp. 9-10)

The DOJ is wrong on the law. As explained in Abbott's spoliation memorandum (and unrebutted by any authority cited by the DOJ), a party has a clear obligation to preserve or produce responsive documents within its control. (Abbott Mot. 9); In re NTL Sec. Litig., Inc., 244 F.R.D. 179, 195 (S.D.N.Y. 2007) (duty to preserve evidence extends to evidence a party has "right, authority, or practical ability" to obtain from a non-party); see also Rosie D. v. Romney, 256 F. Supp. 2d 115, 118-19 (D. Mass. 2003) (holding that state Medicaid officials "controlled," and were required to produce, Medicaid documents held by non-defendant agencies); Calzaturficio v. Fabiano Shoe Co., 201 F.R.D. 33, 38-39 (D. Mass. 2001) ("Control is defined not only as possession, but as the legal right to obtain the documents requested upon demand." (quotation marks and citation omitted)); McKesson Corp. v. Islamic Republic of Iran, 185 F.R.D. 70, 78 (D.D.C. 1999 (holding that agency relationship establishes control over documents); Resolution Trust Corp. v. Deloitte & Touche, 145 F.R.D. 108, 110 (D. Colo. 1992) (holding party had "control" over documents it could obtain by statute). The DOJ acknowledges that Medicaid is a joint federal and state program. (DOJ Rox SJ Opp. 13). And the reasons why any State Medicaid program decided to pay a particular provider a specific amount on any of the claims at issue here necessarily entails an examination of the actual Medicaid claims data. See In re Average Wholesale Price Litig., 478 F. Supp. 2d 164, 180 (D. Mass. 2007) (dismissing portion of California's Medicaid claims because state did not establish link between alleged wrongdoing and the state's MAC payments, which "ceased to be based on prices [allegedly] falsely reported by defendants"); Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 147-48 (D. Mass. 2008) (granting defendants' summary judgment motion where reimbursement did not adhere to CMS-approved State Medicaid plan, or payment regulations). Given that the State Medicaid agencies are joint participants in the Medicaid program with CMS, which has the authority to obtain pertinent information from the states, State Medicaid data is clearly within the "control" of the federal government. *See* 42 U.S.C. § 1396a(a)(6), (42), (69); *see also Calzaturficio*, 201 F.R.D. at 38-39; *Resolution Trust Corp.*, 145 F.R.D. at 110. None of the cases cited in the DOJ's response are to the contrary.⁵

Having no response to this precedent, the DOJ ignores it and instead argues, based on a discussion at a November 13, 2008 hearing, that this Court made a "ruling" regarding the DOJ's obligation to seek Medicaid data from the states: "Implicit in the Court's ruling was the recognition that the United States had no obligation to produce state-level data that the United States did not possess." (DOJ Opp. at 10) Again, the DOJ is wrong. Far from "ruling" that the DOJ did not need to produce state claims data, this Court instructed DOJ counsel: "You should have produced it." (Ex. I, 11/13/08 H'rg Tr. at 34) At the same hearing, this Court also noted about the DOJ's failure to collect the claims data: "If they don't have it, they don't have it, which means they may lose on those claims because I can't create something out of nothing." (Id. at 35)

_

In fact, the cases the DOJ cites are completely inapposite to the factual situation here: they do not involve the government or a governmental agency with access to data that could be readily requested by statute. *See Townsend v. Amer. Insulated Panel Co.*, 174 F.R.D. 1, 5 (D. Mass. 1997) (holding that plaintiff restaurant manager had no obligation to prevent the loss or destruction of a walk-in freezer that was owned by her employer, the restaurant, and sold three years after she was injured when the restaurant vacated the premises); *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 587 F. Supp. 180, 189 (D.D.C. 1984) (holding that defendant Lockheed Aircraft Corporation had no ability to preserve or produce crash investigation photographs taken and maintained by the Air Force). Further, the DOJ's argument that it only had a duty to preserve documents when it had "knowledge or warning of [their] destruction" is at odds with caselaw stating, without such a limitation, that a litigant has a duty to preserve foreseeably relevant evidence. (DOJ Opp. 11 n.8); *Zubulake*, 220 F.R.D. at 216.

II. ROXANE HAS BEEN PREJUDICED BY THE DOJ'S SPOLIATION.

The DOJ's argument that Roxane was not prejudiced by the DOJ's failure to produce the Redbook databases is wrong. Roxane was entitled to obtain full discovery on these Redbook CDs across all four DMERCS. It could not do so because all the evidence has not been produced—even as of today. By withholding these CDs until now, the DOJ deprived Roxane of any opportunity to cross-examine certain DMERCs or the DOJ's experts with this information, and also prevented Roxane from incorporating this evidence into its summary judgment briefing currently before the Court. Roxane's prejudice is only heightened by the fact that the DOJ is relying on the DMERCs' use of these Redbook CDs to fabricate astronomical damages of over \$1 billion.

Rather than address these issues of prejudice, the DOJ instead argues that this data is purportedly "irrelevant" given that the DMERCs' classification of Novaplus ipratropium bromide was "correct." (DOJ Opp. 7-8) As discussed above, the general argument that this evidence is "irrelevant" is flatly contradicted by the DOJ's own litigation-driven declarations and the Redbook CDs themselves. The DOJ's more-specific argument that this evidence is rendered "irrelevant" because three of the four DMERCs were "correct" in classifying Novaplus as a brand is based on nothing more than the DOJ's *ipse dixit* statements —the entire record evidence is to the contrary, including the fact that the DMERCs did not consistently classify Novaplus products as brands, much less get the classification correct. (Dkt. No. 6425, Rox. SJ Reply 11-17) Indeed, the very Redbook CDs that the DOJ withheld demonstrate the DMERCs' errors because these CDs classify the products as generics. (Exs. A, B)

In any event, the DOJ's argument that the evidence is "irrelevant" ignores the fundamental tenet of the adversary system that allows Roxane to test the DOJ's assertions of fact. The DOJ's position allows it to be the sole arbiter of whether evidence is "relevant" or not,

depending on its own assessment of the ultimate merits of its claim. This, of course, is not the law.

With respect to the State Medicaid claims data, Roxane is prejudiced if the DOJ is allowed to proceed on claims for which it has not produced the actual State Medicaid claims data. In fact, the DOJ admits that SMRF/MAX/MSIS data it relies upon to establish both liability and damages does not reflect whether reimbursement was *actually paid* based on Roxane's AWPs or WACs, or whether Roxane's AWPs or WACs were even incorporated into a claim. (Rox. Mot. 8; Dkt. No. 6425, Rox. SJ Reply 20-23) The DOJ admits that: "the datasets contained in the SMRF/MAX/MSIS data do not contain the data required to calculate the basis of payment for a claim" and the SDUD data is *aggregated* data, which likewise can never reveal the basis of payment on any claim. (US Rox. 56.1 Resp. ¶ 267-68)

Thus, despite the DOJ's protestations, the State Medicaid data does not merely affect calculation of damages; this data speaks directly to the issue of liability. In short, the DOJ cannot prove a false claim without proving that payment was made based on Roxane's AWPs or WACs, and only State Medicaid data can reveal whether that occurred. (Dkt. No. 6425, Rox. SJ Reply 20-23) Thus, to the extent that the DOJ is allowed to use the CMS data (*i.e.*, the SMRF/MAX/MSIS/SDUD data) to circumvent this critical predicate inquiry, Roxane is prejudiced.

III. SANCTIONS ARE WARRANTED.

Assuming this Court enters a finding of spoliation on either of these issues, sanctions are warranted. The DOJ effectively concedes that it never recovered, retained, or produced documents within its control and never conducted a fulsome search for pertinent materials as soon as litigation against Roxane became foreseeable. Such conduct is sanctionable. *See, e.g.*, *Testa v. Wal-Mart Stores, Inc.*, 144 F.3d 173, 177 (1st Cir. 1998); *Blinzler v. Marriott Int'l, Inc.*,

81 F.3d 1148, 1159 (1st Cir. 1996). Worse yet, by refusing to ask its contractors or the states for pertinent requested evidence until the eleventh hour, the DOJ withheld critical evidence from Roxane until after it filed its motion for summary judgment. *See First Bank of Marietta v. Hartford Underwriters Ins. Co.*, 307 F.3d 501, 518 (6th Cir. 2002) (no abuse of discretion to sanction party for withholding material evidence); *Daval Steel Prods v. M/V Fakredine*, 951 F2d 1357, 1365 (2d Cir. 1991) (imposing sanctions for a party's failure to disclose "facts essential to an adjudication on the merits, severe sanctions are appropriate."). Only now, after Roxane filed its motion for sanctions, did the DOJ finally produce a portion of this evidence, revealing for the first time the magnitude of the information it has withheld in this case. Such conduct is sanctionable.

CONCLUSION

For all the foregoing reasons and the reasons stated in the Roxane's Motion for Spoliation Sanctions, the Court should grant the Roxane Defendants' Motion for A Finding of Spoliation of Evidence and for Sanctions.

Dated: October 16, 2009 Respectfully submitted,

/s/ Eric T. Gortner

Helen E. Witt, P.C. Anne M. Sidrys, P.C. Eric T. Gortner John W. Reale KIRKLAND & ELLIS LLP 300 North LaSalle Street Chicago, IL 60654

Telephone: (312) 862-2000 Facsimile: (312) 862-2200

Counsel for Defendants Boehringer Ingelheim Corp., Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Roxane, Inc., and

Roxane Laboratories, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on October 16 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ Eric T. Gortner

Eric T. Gortner